

Description of DE10118999

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The invention relates to the use of hormone-free combined preparations, which contain plant components with OS-trough-like effect, to the Vorbeugung and treatment of klimakterischen complaints with men.

It is known that in courses of the normal aging process with men by those relative strong increase of the binding protein SHBG (Sex of hormones being thing of globulins) decreases both the concentration of the free testosterone and those of the free estrogen continuous. Therefore for instance 45 shows up starting from that. Lebensjahr of symptoms of the so-called. Klimakterium virile ("Andropause"), which can step in the form of exhaustion conditions, provokingness, decressive detunings. leaving efficiency and reduced Libido into appearance.

There is specific acting hormone preparations in different dosage forms known, with which the sunk Testosteronspiegel of the man raised or balanced and the androgen-based complaints (in particular a leaving Libido and a erektilen dysfunction) can become counteracted.

However the importance became low content at free estrogens in the male hormone household only since shorter time precise recognized, and this specific change become the more general symptoms of the Andropause (neuro vegetative disturbances such as z. B. Exhaustion conditions, provokingness, depressive detunings, sleep and falling asleep disturbances, leaving efficiency) assigned.

In the sequence series of testosterone and estrogens contained combined preparations became described, with which with the aging man both androgen and the OS trough mirror increased and the developed Hormonimbalancen balanced to become to be able, z. B. the methods of the US patent application US 5,340,586 and the German patent specification DE 196 19 045 c1.

Over therapeutic experiences to the balance of the OS trough deficit with men in the Andropause reported V. Rimkus ("the man in the change of its years", 2000). It describes the medicamentous use in detailed case studies from estrogens (in particular of 17 - beta - estradiols and Östradiolhemihydrat) and explained that to the avoidance of undesirable side effects of the OS trough gift (z. B. the occurrence of a Gynākomastie) narrow an indication position, linked with a regular medical monitoring of the patient during the therapy, displayed is.

Rimkus points in this connection also to the weak OS-trough-like effect from "secondary plant components" or Phytoöstrogenen (z. B. Isoflavones from soy, Bienenpollenextrakten/Gelée Royal), the predominant to the treatment and/or. Vorbeugung of change yearly complaints with women used become. Many of the combined preparations with Phytoöstrogenen can in Germany and in some other countries, contrary to the prescription-requiring östrogenhaltigen drugs, when dietary foods become or brought as food auxiliary means in the trades.

The medical regulation of estrogens to men in the Andropause can adjust the occurred waste of the OS trough mirror, for frequent however the psychological-mental problems arising with the change

yearly complaints and/or, depressive detunings do not repair (Rimkus).

For the invention the object is appropriate to reasons to work against the complaints caused by a too low OS trough mirror with men in the Andropause by the use of OS-trough-free combined preparations in the manner that beside the typical klimakterischen complaints also psychologicalmental accompaniments, in particular depressive detunings, improved and/or, avoided to become to be able.

This object becomes according to invention by the 3 use of such combined preparations dissolved. stated in the claims 1 and, which contain both plant components with OS-trough-like effect (Phytoöstrogene) and substances with psychovegetativer effect.

A special arrangement form of the invention process considered also the therapy and prophylaxis of cell damages, which become caused by free radicals ("oxidative stress") and with aging men because of the lowered OS trough mirror increased to arise to be able, because the radical-catching effects of the estrogens are not sufficient to its prevention or elimination. The cell damages can lead to kardiovakulären diseases, arteriosclerosis, Arthritis/Arthrose or memory disturbances, From the German patent specification DE 34 17 857 C2 and from the where patent application WHERE 98/33495 is known that (and. A.) Ubichinon Q10 with the prophylaxis and therapy of these diseases a synergetic effect to exercise can.

In this special arrangement form of the invention, which is in the claims 2 and 3 described, such combined preparations become used, which contain anti-oxidative acting fabrics, preferably Ubichinon Q10 and/or vitamin E and/or selenium and/or L-methionine, beside Phytoöstrogenen (and fabrics with psychovegetativer effect) as other ingredients.

A ton The use according to invention of the combined preparations is preferably also characterised in that in the preparations as plant components with OS-trough-like effect (Phytoöstrogene) according to claim 4 isoflavonhaltige Sojaextrakte and/or Genistein and/or Daizein and/or Glycitin and/or Equol and/or Coumestrol and/or bloom polling and/or Gelée Royale and/or rotklee and/or hop and/or oats extracts is contained. Stand for the single substances of the plant components corresponding Epimere or chemical identical synthetic compounds, in particular Genistein or Daizein or Glycitin or

The use according to invention of the combined preparations in accordance with one of the claims 1 or 3 is preferably characterised in that the preparations as component with psychogetativer effect either

- absorbing acting ingredients, in particular valerian, hop, Melissen, or passion flower extracts, or - anti-depressive/exciting acting ingredients, in particular caffeine. Hypericin, Kaya Kaya or Johanniskraut extracts.

contained. The choice between a prescription with absorbing or with anti-depressive, relevant for the use of the preparations./exciting acting ingredients after the indication position or the income recommendation ("in the morning/in the evening") one meets.

Furthermore the use according to invention of the combined preparations is preferably characterised in that the preparations contained of the several subsequent active ingredients as other ingredients or:

- Vitamins, in particular Provitamin A (beta carotene), vitamin A, vitamin C, vitamins of the Bseries, vitamin K, pantothenic acid, folic acid, biotin, and/or
- Mineral materials, trace elements, in particular calcium, magnesium, potassium, iron. phosphorus, zinc, manganese, molybdenum, chromium, and/or
- Fabrics with androgener effect, in particular Yohimbin, Ginseng or Gingko.

their derivatives, z. B. Ester, lactones or Glykoside, same.

The use according to invention of the combined preparations is furthermore characterised in that it in the form of tablets, dragees, capsules, ointments, suppositories, gels or compacts used becomes.

In an orienting examination of the use according to invention of the combined preparations a preparation in cap form was ordered for 7 men in the age between 49 and 58 years (ingestion: 2x daily), which contained the subsequent ingredients:

- 50 mg Genistein
- 10 mg Daidzin
- 2 mg Glycitin
- 100 mg Rotklee (Trifolii pratensis flos)
- 100 mg Kava Kava (root thick excerpt, according to. 50 mg Kavalactone)
- pharmaceutical adjuvants ad 350 mg.

All patients pointed before starts of the treatment with less than 1.0 pg/ml estradiols i. S. (Minimum value) and/or. 4,8 pg/ml estradiols i. S. (Maximum value) old-based to low OS trough values on (appoximate value: 6,0-44,0 pg/ml estradiols i. S.), 5 patients complained about significant psycho and neurovegetative complaints, in particular about depressive detunings, unrest conditions, efficiency lacking, in and Durchschlafstörungen or lack of concentration. The subjective condition of the patients became regular determined on the basis a questionnaire in distances of three weeks, in the same time interval became the Östradiolwerte controlled.

After 6 weeks reported altogether 5 of the 7 patients over significant improvements of the psychovegetativen symptoms, 1 patient was already free and (Östradiolwert: 15,8 pg/ml i. S.). With the final study after 9 weeks 6 of the 7 patients subjective was free and, and the Östradiolwerte in the serum was significant increased (8.3/10.5/12.0/17.3/18.2/18.6 pg/ml - a value unchanged: bottom 1.0 pg/ml).

The described uses of combined preparations for Vorbeugung and treatment of klimakterischen complaints with men and their orienting examination of patients are only examples of the use according to invention of these preparations, the invention are not on these examples limited.